



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/298,121	04/23/99	MARCHIONNI	M 04585/044001

KRISTINA BIEKER BRADY PHD
CLARK & ELBING LLP
176 FEDERAL STREET
BOSTON MA 02110

HM12/0117

EXAMINER

NOLAN, P

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/298,121

Applicant(s)

Marchionni et al.

Examiner
Patrick Nolan

Group Art Unit
1644



☒ Responsive to communication(s) filed on Oct 30, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-26 is/are pending in the application.

Of the above, claim(s) 5-8 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 and 9-26 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 and 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

1. Claims 1-26 are pending.

2. Applicant's election without traverse of Group I, claims 1-4 and 9-28 drawn to treating congestive heart failure with NRG-1 polypeptide in Paper No. 10 is acknowledged.

Accordingly, claims 5-8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4 and 9-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claimed invention is drawn to treating congestive heart failure by the administration of a NRG-1 polypeptide. The state of the art, The Merck Manual of Diagnosis and Therapy, does not recognize the use of the NRG-1 polypeptide for the treatment of any of the multiple causes of congestive heart failure (pages 1688-1692, in particular). Congestive heart failure is a complex in vivo disease which has many causative factors, Applicant's specification has no in vivo working examples demonstrating that administration of the NRG-1 polypeptide treats any form of congestive heart failure. Since the state of the art does not recognize NRG-1 treatment for any form of congestive heart failure and applicant's have no in vivo working examples demonstrating congestive heart failure treatment and the state of the art does not recognize that their in vitro data would reasonably correlate to in vivo treatment it would be unpredictable and require an undue amount of experimentation to practice Applicant's claimed invention.

5. Applicant is notified that reference Zhao et al., on the IDS received 7-7-00 was crossed out because it was a duplicate of the Zhao et al., reference submitted on the IDS received 10-20-00

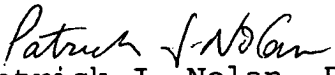
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can

Serial Number: 09/298,121
Art Unit: 1644

3

normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.


Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
January 16, 2001